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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,831	11/24/2003	Richard A. Berg	C94-018-D2	2955

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EXAMINER	
PROUTY, REBECCA E	
ART UNIT	**PAPER NUMBER**
1652	

NOTIFICATION DATE	DELIVERY MODE
12/03/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/720,831	BERG ET AL.	
	Examiner	Art Unit	
	Rebecca E. Prouty	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-9,14-16 and 18-20* is/are pending in the application.

4a) Of the above claim(s) *18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-9,14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

In view of the appeal brief filed on 9/11/07, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below.

Claims 6, 10-13, and 17 have been canceled. Claims 1-5, 7-9, 14-16, and 18-20 are at issue and are present for examination.

Claims 18-20 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected

invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/16/06.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is incomplete as it depends from a cancelled claim. For purposes of further examination it is presumed this claim was intended to depend from claim 1.

Claims 1-4, 7-9, and 14-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a recombinant procollagen comprising a natural collagen polypeptide chain, a natural C-terminal collagen propeptide, and a first non-natural site-specific proteolytic agent recognition site, wherein said first non-natural site-specific proteolytic agent recognition site is located between said collagen chain and said natural C-terminal collagen propeptide, and further comprising an amino terminal propeptide and a second non-natural site-specific proteolytic agent recognition site, wherein said second non-natural site-specific proteolytic agent recognition site is located between said N-terminal propeptide and said collagen chain, does not

reasonably provide enablement for a recombinant procollagen comprising a natural collagen polypeptide chain and any C-terminal propeptide, and a first non-natural site-specific proteolytic agent recognition site, wherein said first non-natural site-specific proteolytic agent recognition site is located between said collagen chain and said C-terminal propeptide, and further comprising an N-terminal propeptide and a second non-natural site-specific proteolytic agent recognition site, wherein said second non-natural site-specific proteolytic agent recognition site is located between said collagen chain and said amino terminal propeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1-4, 7-9, and 14-16 recite a recombinant procollagen comprising a natural collagen polypeptide chain and any C-terminal propeptide, and a first non-natural site-specific proteolytic agent recognition site, wherein said first non-natural site-specific proteolytic agent recognition site is located between said collagen chain and said C-terminal propeptide, and further comprising an N-terminal propeptide and a second non-natural site-specific proteolytic agent recognition site, wherein said second non-natural site-specific proteolytic

agent recognition site is located between said collagen chain and said amino terminal propeptide and mature or partially processed collagen chains produced by cleaving said procollagens with said first site-specific proteolytic agent. However the art makes it clear that the presence of a natural C-terminal propeptide in a procollagen molecule is absolutely necessary for correct disulfide bond formation, glycosylation and triple helix formation. (See Lukens, Harwood et al., and Rosenbloom et al.). These processes are essential for producing a biologically active collagen protein. The sequences necessary for directing these processes are clearly encoded within the natural C-terminal propeptide sequence and it is highly unlikely that other unrelated sequences could provide for these functions of the natural C-terminal propeptide. Furthermore, neither the specification nor the art provide any guidance for selecting other sequences which would in fact provide for these functions. As such a skilled artisan could not reasonably expect to make and use procollagens which would be useful for making biologically useful collagens using a recombinant procollagen lacking a natural C-terminal propeptide.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lee et al. (1992, see applicants IDS)

Lee et al. teach recombinant production of mature collagen polypeptides and pC-α1(I) and compositions thereof. Lee et al. further teach procollagen proteins including the first 25 amino acids of the natural N-terminal propeptide, followed by the natural human α1(I) collagen and C-terminal propeptide sequences. The sequence separating the shortened N-terminal propeptide from the natural human α1(I) collagen sequence (i.e., Tyr-Leu) comprises a chymotrypsin cleavage site and thus is a procollagen chain comprising a natural collagen polypeptide chain, a first propeptide, and a first non-natural site-specific proteolytic agent recognition site, wherein said first non-natural site-specific proteolytic agent recognition site is located between said collagen chain and said first propeptide, and further comprising a second propeptide. Cleavage of this polypeptide with chymotrypsin would produce pC-α1(I). Although the collagen polypeptides of Lee et al. were not produced from a procollagen protein as recited in claim 1, the collagen proteins produced therefrom following cleavage of the propeptides is not

structurally different from the collagen polypeptides of Lee et al. The use of a 102/103 rejection for the rejection of a product-by-process claim has been approved by the courts. While the references do not specifically disclose the proteins produced by the methods recited in the claims, the production of a protein by a particular process does not impart novelty or unobviousness to a protein when the same protein is taught by the prior art. This is particularly true when the properties of the protein are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this

context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 5 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,653,450. This is a double patenting rejection. Both claims recite a recombinant procollagen comprising a natural collagen polypeptide chain, a natural C-terminal collagen propeptide, and a first non-natural site-specific proteolytic agent recognition site, wherein said first non-natural site-specific proteolytic agent recognition site is located between said collagen chain and said natural C-terminal collagen propeptide, and further comprising an second propeptide and a second non-natural site-specific proteolytic agent recognition site, wherein said second non-natural site-specific proteolytic agent recognition site is located between said second propeptide and said collagen chain.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not

patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 7-9 and 14-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,653,450. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not

patentably distinct from each other because Claims 1-4, 7-9 and 14-16 are generic to all that is recited in claims 1 and 2 of U.S. Patent No. 6,653,450. That is, claims 1 and 2 of U.S. Patent No. 6,653,450 fall entirely within the scope of claims 1-4, 7-9 and 14-16 herein, or claims 1-4, 7-9 and 14-16 are anticipated by claims 1 and 2 of U.S. Patent No. 6,653,450.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/
Primary Examiner
Art Unit 1652

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